

Introduction

Claims 1-8 and 12-15 are pending and have been rejected. Objection has been made to Claim 15 for incorrect claim dependency. Claims 2 and 3 have been rejected under 35 U.S.C. § 112, second paragraph, for insufficient antecedent basis. Claim 7 has been rejected under 35 U.S.C. 112, second paragraph, as having no antecedent basis for “solvates”. Claims 1-8 and 12-15 have been rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. Claims 1-8 and 12-15 have been rejected under 35 U.S.C. § 102(b) as being anticipated by JP50106977, JP50142576, JP5300534, and JP57080322. Claims 1-8 and 12-15 have been rejected under 35 U.S.C. § 102(e) as being anticipated by: U.S. 6,509,357, U.S. 6,710,069, U.S. 6,919,354, and WO2002014273.

Remarks

Claims 6, 12, 13, 14 and 15 have been cancelled without prejudice to the subject matter therein, reserving the right to pursue this subject matter in continuation applications. Claims 1, 2, 3, and 7 have been amended. Claims 2-5 have been amended to clearly indicate they include salts of the compounds of Claim 1, and Applicants submit no new matter has been added by these amendments.

Incorrect claim dependency

Claim 15 has been cancelled.

35 U.S.C. § 112, second paragraph rejections

1) Claims 2 and 3 have been rejected under 35 U.S.C. § 112, second paragraph, for insufficient antecedent basis. Claims 2 and 3 have been amended and now have antecedent basis. Applicants submit no new matter has been added.

2) Claim 7 has been rejected under 35 U.S.C. § 112, second paragraph, as having no antecedent basis for “solvates”. Claim 7 has been amended by deleting “or solvate.” Applicants submit no new matter has been added.

35 U.S.C. § 112, first paragraph rejection

Claims 1-8 and 12-15 have been rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner states that the specification, while being enabling for the compounds wherein

- 1) The heterocyclic ring on the Y is a unsubstituted piperidine does not reasonably provide enablement for the het ring to be a pyrro[l]idine.
- 2) for antagonist activity of selected compounds was tested for inhibition of [35S] GTP T [S] binding to H3R membranes in the presence of agonists for compound 6 and 60. does not provide enablement for the activity as claimed for all other compounds.
- 3) treating and “preventing” obesity and cognitive disorders.
- 4) “pharmaceutical” compositions, i.e. compositions for treating a disease or
- 5) "solvates" of the compounds.

Remarks as to items 1), 3), 4) and 5):

As to item 1), Claim 1 has been amended to delete “-OCH₂CH₂N-pyrrolidinyl and -OCH₂CH₂CH₂N-pyrrolidinyl.” As to items 3) and 4), Claims 12, 13, 14 and 15 have been cancelled. As to item 5), Claim 7 has been amended to delete “or solvate.” Applicants submit no new matter has been added.

Remarks as to item 2)

Applicants respectfully assert that the scope the disclosed Examples is commensurate with the scope of presently amended Claim 1. The present Examples provide clear guidance to one skilled in the chemical art as to how to make and use the present invention. The specification discloses that “[c]ompounds of Formula I are effective as histamine H₃ receptor antagonists. More particularly, these compounds are selective histamine H₃ receptor antagonists that have little or no affinity for histamine receptor GPRv53(H₄R).” (page 65, lines 29-30 to page 66, line 1). The specification describes an assay ([35S] GTP γ [S]) which is used to evaluate the activity by binding to H₃R membranes in the presence of agonists. Applicants respectfully submit that the results for the two compounds tested in the indicated assay are representative of the activity of the examples disclosed in the application. Applicants respectfully submit that it would not be unduly burdensome for one skilled in the art to prepare Examples of the present invention and test them in the [35S] GTP γ [S] assay. Thus, Applicants respectfully assert the specification is enabling of the full scope of the presently amended claims.

Further Remarks to part 4)

As noted above, prior claim 15 has been cancelled without prejudice. Thus, to the extent the Examiner has made a rejection of Claim 8, Applicants respectfully submit the specification fully enables Claim 8 as follows. In the specification, from page 63, lines 28-32 to page 65, lines 1-27, there is description of the preparation of a pharmaceutical composition of compounds of

formula I. On page 63, lines 28-30, it is stated that “another embodiment of the present invention is a pharmaceutical composition comprising a compound of Formula I and one or more pharmaceutically acceptable carriers, diluents or excipients.” Further, on page 64, lines 9-13, there is description of examples of “suitable carriers, excipients, and diluents.” Preferably, the composition comprising a compound of formula I is administered orally (page 65, line 15). “Preferably, the pharmaceutical preparation is in a unit dosage form.” (page 65, line 16). The more preferable unit dosage is from about 0.01 to about 500 milligrams. (page 65, lines 22-23). Applicants respectfully submit that one skilled in the art of pharmaceutical sciences can prepare a pharmaceutical composition of a compound of formula I.

35 U.S.C. § 102(b) rejection

Claims 1-8 and 12-15 have been rejected under 35 U.S.C. § 102(b) as being anticipated by JP50106977, JP50142576, JP5300534, and JP57080322.

Claim 1 has been amended to delete “C(O)” as an option for G². Claim 7 has been amended to delete Example 16 as an option. Applicants submit no new matter has been added. Applicants submit the presently amended claims are not anticipated by JP50106977, JP50142576, JP5300534, or JP57080322.

35 U.S.C. § 102(e) rejections

1) Claims 1-8 and 12-15 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. 6,509,357, U.S. 6,710,069, and U.S. 6,919,354. Claim 1 has been amended to delete “or G¹ and G² taken together combine to form -CH=CH- or -CH₂-CH=CH-.” Claim 7 has been amended to delete Example 64 as an option. Applicants submit no new matter has been added. Applicants submit the presently amended claims are not anticipated by U.S. 6,509,357, U.S. 6,710,069, and U.S. 6,919,354.

2) Claims 1-8 and 12-15 have been rejected under 35 U.S.C. § 102(e) as being anticipated by WO2002014273. Claim 1 has been amended with the proviso “provided the compound is not 6-(2-Piperidin-1-yl-ethoxy)-2,3-dihydro-1H-indole”. Applicants submit no new matter has been added. Applicants submit the present amended claims are not anticipated by WO2002014273.

Conclusion

Applicants respectfully submit that claims 1, 2, 3, 4, 5, 7 and 8 are presently in order for grant.

Respectfully submitted,

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